Statement
of the

American Pharmaceutical Association

The National Professional Society of Pharmacists

Safety Issues Related to Acetaminophen
Food and Drug Administration
Nonprescription Drugs Advisory Committee
September 19, 2002

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Statement of the American Pharmaceutical Association (APhA)
to the Food and Drug Administration's
Nonprescription Drugs Advisory Committee
Safety Issues Related to Acetaminophen and
Nonsteroidal Anti-Inflammatory Drugs
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Thank you for the opportunity to present the views of the American Pharmaceutical Association (APhA), the national professional society of pharmacists. I am Susan Winckler, a pharmacist and an attorney, and APhA's Vice President of Policy and Communications. My comments today will focus on the pharmacist's perspective on the use of acetaminophen, possible sources of problems seen with over-the-counter (OTC) analgesics, and the need for consumer education.

In the interest of full disclosure, APhA frequently partners with Federal agencies, consumer groups, the pharmaceutical industry, and others to develop educational tools for pharmacists and consumers. The Association did not receive funding to participate in today's meeting, and the views I am presenting are solely those of the Association and its membership.

APhA's 50,000 members include pharmacist practitioners, pharmaceutical scientists, student pharmacists, and pharmacy technicians. APhA members provide care in all practice settings such as community pharmacies, hospitals, long-term care facilities, managed care organizations, hospice and the military. In each of these settings, we help consumers manage and improve their medication use – including the appropriate selection and monitoring of prescription and OTC products such as acetaminophen.

Acetaminophen is widely used in both prescription and OTC analgesics and cold, allergy, and sinus preparations. According to the briefing documents for this meeting, over 24 billion units of acetaminophen drug products were sold in the year 2000 alone.[1] Pharmacists, other health care providers, and patients frequently select acetaminophen products because of its excellent safety profile and relatively low number of side effects, and for its appropriateness in special populations such as pediatric patients and patients with asthma, hypertension, or gastrointestinal disorders. It is of significant therapeutic value for millions of patients. However, acetaminophen, like all other drug products, is only safe and effective *when used appropriately.*

Improving the public's health and safety with respect to medication use, is the pharmacist's, and APhA's, highest priority. APhA supports the review of adverse events to determine if a medication's benefits are outweighed by its risks. In the case of acetaminophen, the advisory committee is examining reports of possible safety issues such as acetaminophen-induced hepatotoxicity. While these reports of adverse events are possible indicators of problems, we

[1] Food and Drug Administration. Memorandum on Acetaminophen Utilization and Hepatotoxicity PID#: D010092. August 13, 2002.

warnings information.[6] Consumers must be reminded that any medication – including OTCs – have the potential to harm if used incorrectly. A survey of caregivers found that only 28% were aware that OTCs could have side effects and only 36% could name a possible side effect that could occur for a given medication.[7] Consumers must be encouraged to read product labeling, take the medication as directed, learn of possible side effects, and know what to avoid while taking the medication. Consumers with questions or special needs should also be encouraged to talk to their pharmacist or physician before selecting or taking any new medication or combining multiple products.

APhA also recommends that all prescription and OTC products containing acetaminophen be clearly marked. Patients often identify with the brand name of the medication they are taking, but are not aware of the product's active ingredients. For example, patients may report that they are utilizing the product Tylenol®, but a survey found that only 8% of those individuals would also report using acetaminophen.[8] OTC products should contain verbiage such as "contains acetaminophen" on the product's front panel, preferably in conjunction with the product's name. Acetaminophen-containing prescription drug products could be identified through the use of auxiliary labels placed on the prescription vial by the pharmacist. And both products should include warnings about therapeutic duplication.

We are pleased that Bayer Consumer Care and McNeil Consumer & Specialty Pharmaceuticals and other manufacturers of OTC products have announced the revision of labeling for their acetaminophen-containing products to emphasize the active ingredient and include an overdose warning.[9] APhA encourages the FDA to recognize industry's efforts in this area and to further advance their efforts by allowing important dosing information for pediatric patients under the age of two to be included on the product label. APhA believes that the inclusion of this dosing information may prevent overdoses caused by inaccurate estimations of appropriate doses of child or adult formulations.

In conclusion, I would like to reiterate my belief that acetaminophen is one of the safest and most effective OTC and prescription drug products available for pain relief. It is important that the Agency does not reduce access to this valuable class of pain medications. Instead the Agency should work with product manufacturers, pharmacists, physicians, and consumer groups to educate consumers on the appropriate selection and use of all OTC products including acetaminophen, aspirin, and other non-steroidal anti-inflammatory drugs (NSAIDS). Consumer education activities such as NCPIE's "Be MedWise" public education campaign is a great way to educate consumers about the need to read and follow label directions and to ask their pharmacist if they have any questions. Helping consumers learn how to appropriately select and use OTC medications is key to reducing product overdoses and related adverse events.

Thank you for your consideration of the views of the nation's pharmacists.

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[6] "Attitudes and Beliefs About the Use of Over-the-Counter Medicines: A Dose of Reality." National Council on Patient Information and Education (NCPIE). January 2002. Pg. 5.

[7] Simon, Harold, and Weinkler DA. "Over-the-Counter Medications: Do Parents Give What They Intend to Give?" Archives Pediatric and Adolescent Medicine. July 1997. Pg. 654.

[8] Ibid., Pg. 656.

[9] "Voluntary Acetaminophen Labeling Revisions Include Overdose Warning." The Tan Sheet. September 16, 2002.